Office of Environmental Health Hazard Assessment

Proposition 65
Regulatory Update Project
Warnings for Beneficial Nutrients in Foods
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Welcome and Introduction

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Overview

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Purpose of Proposal

- To provide a limited exemption from the warning requirements of Proposition 65 for exposures to listed chemicals in foods that are necessary for human health
- To provide model warning language for those exposures to listed chemicals in foods that are beneficial nutrients that exceed the level provided in the regulation

Scope of Proposal

- Exposures to chemicals already listed under Proposition 65 that are necessary for human health.
- Some beneficial nutrients can cause cancer or reproductive effects at levels higher than the recommended dose.
- Currently listed examples:
  - Retinol (Vitamin A)
  - Chromium

Scope of Proposal (Cont.)

- This regulation would only apply to chemicals already listed and any that may get listed in the future.
- OEHHA is not proposing the listing of any new chemicals in this regulation.
- Does not regulate the amount of the chemical that can be in the product
- Provides a limited exemption from the warning requirements for certain exposures
- May add specific warning language for exposures above the specified levels

Current Proposed Regulatory Language

- (a) Human consumption of a food shall not constitute an “exposure” for purposes of Section 25249.6 of the Act to a listed chemical in a food if the person causing the exposure to the chemical can show that the chemical is a nutrient that is beneficial to human health and that the total amount of the chemical consumed in a food, whether naturally occurring, intentionally added to the food, or otherwise present, does not exceed the level established in subsection (c).

Proposed Regulatory Language (cont.)

- (b) For purposes of this section, a chemical is beneficial to human health if a daily value or allowance has been established for the chemical or compound by the Food and Nutrition Board of the Institute of Medicine, National Academies.

Proposed Regulatory Language (cont.)

- (c) This section applies only to exposures that do not exceed the Recommended Daily Allowance (RDA) established in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine, National Academies, current edition, if one is established. If no RDA is established, this section applies only to exposures that do not exceed 20 percent (20%) of the Tolerable Upper Intake Level established in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine, National Academies, current edition.

Food & Nutrition Board DRI table

Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Vitamins

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Vit A (µg/d)[a]	Vit C (mg/d)	Vit D (µg/d)[b,c]	Vit E (mg/d)[d]	Vit K (µg/d)	Thiamin (mg/d)	Riboflavin (mg/d)	Niacin (mg/d)[e]	Vit B_6 (mg/d)	Folate (µg/d)[f]	Vit B_{12} (µg/d)	Pantothenic Acid (mg/d)	Biotin (µg/d)	Choline[g] (mg/d)
Infants														
0–6 mo	400*	40*	5*	4*	2.0*	0.2*	0.3*	2*	0.1*	65*	0.4*	1.7*	5*	125*
7–12 mo	500*	50*	5*	5*	2.5*	0.3*	0.4*	4*	0.3*	80*	0.5*	1.8*	6*	150*
Children														
1–3 y	300	15	5*	6	30*	0.5	0.5	6	0.5	150	0.9	2*	8*	200*
4–8 y	400	25	5*	7	55*	0.6	0.6	8	0.6	200	1.2	3*	12*	250*
Males														
9–13 y	600	45	5*	11	60*	0.9	0.9	12	1.0	300	1.8	4*	20*	375*
14–18 y	900	75	5*	15	75*	1.2	1.3	16	1.3	400	2.4	5*	25*	550*
19–30 y	900	90	5*	15	120*	1.2	1.3	16	1.3	400	2.4	5*	30*	550*
31–50 y	900	90	5*	15	120*	1.2	1.3	16	1.3	400	2.4	5*	30*	550*
51–70 y	900	90	10*	15	120*	1.2	1.3	16	1.7	400	2.4[i]	5*	30*	550*
> 70 y	900	90	15*	15	120*	1.2	1.3	16	1.7	400	2.4[i]	5*	30*	550*
Females														
9–13 y	600	45	5*	11	60*	0.9	0.9	12	1.0	300	1.8	4*	20*	375*
14–18 y	700	65	5*	15	75*	1.0	1.0	14	1.2	400[j]	2.4	5*	25*	400*
19–30 y	700	75	5*	15	90*	1.1	1.1	14	1.3	400[j]	2.4	5*	30*	425*
31–50 y	700	75	5*	15	90*	1.1	1.1	14	1.3	400[j]	2.4	5*	30*	425*
51–70 y	700	75	10*	15	90*	1.1	1.1	14	1.5	400	2.4[h]	5*	30*	425*
> 70 y	700	75	15*	15	90*	1.1	1.1	14	1.5	400	2.4[h]	5*	30*	425*
Pregnancy														
14–18 y	750	80	5*	15	75*	1.4	1.4	18	1.9	600[j]	2.6	6*	30*	450*
19–30 y	770	85	5*	15	90*	1.4	1.4	18	1.9	600[j]	2.6	6*	30*	450*
31–50 y	770	85	5*	15	90*	1.4	1.4	18	1.9	600[j]	2.6	6*	30*	450*
Lactation														
14–18 y	1,200	115	5*	19	75*	1.4	1.6	17	2.0	500	2.8	7*	35*	550*
19–30 y	1,300	120	5*	19	90*	1.4	1.6	17	2.0	500	2.8	7*	35*	550*
31–50 y	1,300	120	5*	19	90*	1.4	1.6	17	2.0	500	2.8	7*	35*	550*

NOTE: This table (taken from the DRI reports, see www.nap.edu) presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy breastfed infants, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

[a] As retinol activity equivalents (RAEs). 1 RAE = 1 µg retinol, 12 µg β-carotene, 24 µg α-carotene, or 24 µg β-cryptoxanthin. The RAE for dietary provitamin A carotenoids is twofold greater than retinol equivalents (RE), whereas the RAE for preformed vitamin A is the same as RE.

[b] As cholecalciferol. 1 µg cholecalciferol = 40 IU vitamin D.

[c] In the absence of adequate exposure to sunlight.

[d] As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of α-tocopherol (*RRR*-, *RSR*-, *RRS*-, and *RSS*-α-tocopherol) that occur in fortified foods and supplements. It does not include the *2S*-stereoisomeric forms of α-tocopherol (*SRR*-, *SSR*-, *SRS*-, and *SSS*-α-tocopherol), also found in fortified foods and supplements.

[e] As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan; 0–6 months = preformed niacin (not NE).

[f] As dietary folate equivalents (DFE). 1 DFE = 1 µg food folate = 0.6 µg of folic acid from fortified food or as a supplement consumed with food = 0.5 µg of a supplement taken on an empty stomach.

[g] Although AIs have been set for choline, there are few data to assess whether a dietary supply of choline is needed at all stages of the life cycle, and it may be that the choline requirement can be met by endogenous synthesis at some of these stages.

[h] Because 10 to 30 percent of older people may malabsorb food-bound B_{12}, it is advisable for those older than 50 years to meet their RDA mainly by consuming foods fortified with B_{12} or a supplement containing B_{12}.

[i] In view of evidence linking folate intake with neural tube defects in the fetus, it is recommended that all women capable of becoming pregnant consume 400 µg from supplements or fortified foods in addition to intake of food folate from a varied diet.

[j] It is assumed that women will continue consuming 400 µg from supplements or fortified food until their pregnancy is confirmed and they enter prenatal care, which ordinarily occurs after the end of the periconceptional period—the critical time for formation of the neural tube.

Questions for Discussion

- Should certain exposures to listed chemicals in foods be exempted from the Prop 65 warning requirements?
- Should the language in the proposed regulation be modified? If so how?
- Should OEHHA consider proposing specific warning language for those exposures that do require a warning?

Wrap-Up

- Next Steps
- Comments due by May 2, 2008
- Provide comments to:
  - Fran Kammerer
  - 1001 “I” Street
  - Sacramento, CA 95814
  - fkammerer@oehha.ca.gov
  - (916) 445-4693
- More public comment opportunities to follow.